

Notice of Allowability	Application No.	Applicant(s)	
	10/595,049	HAMMERBECK ET AL.	
	Examiner	Art Unit	
	BLESSING FUBARA	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/20/2011.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1, 3-7, 20, 21, 35-37, 39, 41, 43, 45 and 49 (claims are renumbered 1-16).
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>See Continuation Sheet</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>03/07/2012</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
|--|---|

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 08/09/2011; 01/17/2012.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ted K. Ringsred on 03/07/2012.

The application has been amended as follows:

in the claims, amend claim 36 as follows:

36. (Withdrawn Currently amended) A method for delivering an immune response modifier to a nasal passage of a subject, the method comprising:

selecting a formulation comprising:

an immune response modifier, wherein the immune response modifier is N-{2-[4-amino-2-(ethoxymethyl)-1H-imidazo[4,5-c]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide, or a pharmaceutically acceptable salt thereof;

water; and

a hydrophilic viscosity enhancing agent;

with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;

wherein the formulation is a solution at room temperature and has a viscosity of less than 100 cps at room temperature, and is contained in a nasal spray device; and applying the selected formulation into a nasal passage of a subject.

In the claims:

Amend claims 37, 39, 41 and 43 as follows:

37. (Withdrawn, Currently Amended) A method of treating ~~and/or preventing~~ allergic rhinitis, the method comprising applying the formulation of claim 1 into a nasal passage or a subject.

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39. (Withdrawn, Currently Amended) A method of treating ~~and/or preventing~~ a viral infection, the method comprising applying the formulation of claim 1 into a nasal passage of a subject.

41. (Withdrawn, Currently Amended) A method of treating ~~and/or preventing~~ sinusitis, the method comprising applying the formulation of claim 1 into a nasal passage of a subject.

43. (Withdrawn, Currently Amended) A method of treating ~~and/or preventing~~ asthma, the method comprising applying the formulation of claim 1 into the respiratory tract of a subject.

Amend the specification as follows:

On page 1, amend the paragraph immediately following the “CROSS-REFERENCE TO RELATED APPLICATIONS” section as follows:

This application is a 371 of PCT/US04/25277 filed 08/05/2004 and which ~~This application~~ claims priority to U.S. Provisional Application Serial No. 60/493,109, filed August 5, 2003, which is incorporated herein by reference in its entirety.

Reasons for Allowance

2. The following is an examiner’s statement of reasons for allowance: The prior art to Hedenstrom while disclosing a composition comprising immune response modifier, water and hydrophilic viscosity enhancing agent such as acrylic acid polymer, CARBOMER (see at least column 24, lines 10-19) for use in the nasal, buccal and tracheal surfaces, Hedenstrom does not teach the specific IRM of the claims. It is the examiner’s opinion, it would not have been obvious to a person of ordinary skill in the art to select the claimed IRM from the various IRM for the composition of Hedenstrom.

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3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Rejoinder:

5. Claims 1, 3-7, 20, 21, 35 and 49 are allowable. Claims 36, 37, 39, 41, 43 and 45, previously withdrawn from consideration as a result of a restriction requirement, requires all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), **the restriction requirement between inventions I-V, as set forth in the Office action mailed on 08/14/2009, is hereby withdrawn** and claims 36, 37, 39, 41, 43 and 45, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

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7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613